

1 use this device with respect to body cell mass wasting.

2 (Discussion off the record.)

3 THE COURT: Okay.

4 MS. CARMODY: Body cell mass, in terms of the
5 criteria the FDA looked at and the company looked at in the
6 testing trials, they looked at lean body mass and never looked
7 at body cell mass. And body cell mass is not something that
8 can be seen, it's the only measure -- if there is a measure,
9 and there's a lot of difference of opinion even today in the
10 medical community whether or not there is any way to accurately
11 measure body cell mass in any individual.

12 The software that the company developed with and
13 through RJL -- and RJL is a very small, less than ten person
14 operation just outside of Detroit. It was one of the few
15 manufacturers of this kind of device in the country, and they
16 went -- the company went to RJL as early as 1995 and was
17 talking about the BIA device; but the conspiracy really began
18 in 1996 when they changed the software that was used to
19 accompany the BIA device. And there were four different kinds
20 of software --

21 THE COURT: Did RJL do that software?

22 MS. CARMODY: RJL worked with the company to
23 develop the software.

24 THE COURT: Developed the software.

25 Is RJL then a co-conspirator here?

1 MS. CARMODY: RJL is a co-conspirator here, and
2 they have been charged in an information in a related case.
3 The company and the president have both pled guilty to an
4 information charging similar -- charging essentially this
5 conspiracy last April, and they're due for sentencing in
6 February of 2006.

7 THE COURT: Okay.

8 MS. CARMODY: They developed in 1994 the FNA
9 software.

10 And I won't go into the particulars of each
11 software. I'll rely on the sentencing memorandum for that.

12 But the important parts of this particular
13 development, because it was the first in the long line of
14 development, was that the prediction equation that -- and in
15 order to get the readings from the BIA device, they have to put
16 the readings of reactants and resistance into the computer
17 software using a predictive equation based upon a particular
18 patient or population to determine how the person that's being
19 tested measured up to some kind of a normal or otherwise
20 population.

21 The predictive equation is used to estimate the BCM
22 based upon the measurements of total body potassium, that was
23 in the FNA software. That's a different base than was used in
24 the prior device that the RJL had had approved by the FDA.

25 They also used a different patient population, a

1 different database, this time consisting of about 332 humans
2 who were either healthy or had tested for HIV. Very different
3 patient population than the device had been approved for in the
4 1980s.

5 So RJL, together with Serono -- and there were
6 several people from Serono, people that worked in the marketing
7 department as well as people in the medical affairs department
8 that worked together to develop this computer software to see
9 whether or not they could determine body cell mass and whether
10 or not that could be used as a criteria to determine whether
11 someone was suffering from AIDS.

12 But this patient -- this equation, this device with
13 a different equation and a different database, was also being
14 used for a different purpose than the device was being used in
15 the 1980s; and that was specifically to determine whether
16 someone had the redefined AIDS wasting. And that, in fact, was
17 the new and intended use that is the basis for the crime with
18 respect --

19 THE COURT: Not approved by the FDA.

20 MS. CARMODY: It was never approved -- they never
21 even applied for any kind of approval from the FDA.

22 So they went from FNA software that was being
23 used -- and, by the way, your Honor, not only were they using
24 it to define within the company, but what they did with the
25 devices was they sent the devices to physicians. The company

1 had a different progression with respect to the devices. The
2 devices themselves cost about -- on retail about \$4,500,
3 \$4,900.

4 The company made a major purchase where they paid
5 about \$2,500 for each device, and they wanted first to lease it
6 or to sell it to doctors. They didn't get enough interest in
7 doctors of leasing it and selling it, so they then decided to
8 give it away to doctors, because they had to put these devices
9 in the doctors' offices in order for the doctors to go beyond
10 that scale into body cell mass wasting.

11 So what they also did was train their employees not
12 only on how to do the tests, and the employees went in and both
13 showed doctors and their staffs how to perform the tests, but
14 also did the tests themselves.

15 The second software that was developed between the
16 company and RJL was in about 1998 it incorporated the same
17 equation that was used in the FNA software, but they measured
18 it against a different population base so that they would get
19 different results. Because this was a database of humans
20 derived from something called the National Health and Nutrition
21 Examination Survey, often referred to as NHANES; and this new
22 software which was also used by company employees and
23 disseminated to doctors' offices, and this is throughout the
24 United States, was required premarket approval from the FDA
25 before its introduction, and no such approval was either sought

1 or obtained.

2 The next software was developed in about August of
3 1999, and that's the SomaScan software. And I would point out
4 one thing, your Honor, because I think it's important. We did
5 submit as part of the offense conduct, it's not public, but it
6 is referred to in the presentence report, the summary of the
7 total Medicaid reimbursement, not just for Medicaid but for
8 other federal programs, and it shows the sales over the years.

9 And your Honor will notice that the sales increased
10 in 1998 but went up exponentially in 1999 and 2000. And this
11 was about the same time of the introduction of the SomaScan
12 software was being developed and disseminated to the employees
13 of Serono for their use and for doctors' use.

14 After this particular software, in addition to
15 using that same predictive equation again for estimating body
16 cell mass, among other things, it further computed the
17 purported precise ideal amounts for each of these measurements
18 for individual test subjects and compared them to this NHANES
19 database. But the key here is they eliminated any standard
20 deviation from its calculations, which absolutely skewed the
21 results.

22 The results were so skewed that when employees were
23 given the software, they were told to retest patients so that
24 when they retested patients who had already tested and not
25 shown to be wasting, these new patients would actually -- were

1 actually shown to have been wasted.

2 This was also a new and intended use, and it
3 required premarket approval from the FDA before introduction
4 into interstate commerce, and no approval was sought or
5 obtained.

6 And, finally, the fourth variation on the software
7 was Cyprus 1.2 condensed. It was introduced in February of
8 2000. And during the period of time, especially, in
9 particular, in 1999, the problems with the SomaScan software
10 was something that was a priority at the company. This was
11 something that was so out of whack, so to speak, with the
12 results that they had received previously, that it was a real
13 focus of attention.

14 So that they tried, again, to revise the software
15 to determine whether or not they could come up with anything
16 that would be the gold standard or validated results with
17 respect to these tests.

18 So Cyprus 1.2 then computed purported normal
19 amounts and normal ranges, again, using the Z equation, as we
20 call it; and this, again -- a portion of the NHANES database
21 but a different patient population in that NHANES database.

22 This was also a new and intended use. It required
23 premarket approval, and no such approval was either submitted
24 or obtained.

25 What the company -- and I've already alluded to

1 it -- was doing with this software, which was its primary
2 marketing tool, and one particular document that stands out in
3 my mind in terms of company documents was one e-mail done by
4 the company's medical director that said -- referred to how
5 tests ought to be performed and said although we don't market
6 solely using the BIA test -- so even the medical affairs people
7 in the company, as well as the marketing and sales people, knew
8 that this device was being used to market its product.

9 The only purpose of this device was to redefine and
10 expand the definition of AIDS wasting into an area that the FDA
11 had never approved. And they went as far as to measure amounts
12 of their employees' time as to how much time they were spending
13 doing BIAs; and, in particular, used something called the BIA
14 hit rate, which is measuring how many prescriptions they would
15 obtain after doing how many BIA tests. So that they were
16 measuring the success of using this tool that had never been
17 approved by the FDA for the purpose for which they were using
18 it.

19 THE COURT: And the point of this, as I understand
20 it, the government to be charging is the point of this device
21 is to show people that, notwithstanding how they looked, what
22 they -- the fact that they might be gaining weight, they still
23 had body wasting and they needed the drug.

24 MS. CARMODY: Exactly, your Honor.

25 THE COURT: And then they go out and buy the drug.

1 MS. CARMODY: Exactly, your Honor.

2 Now, the primary -- and this is important
3 particularly with respect to the Court's comment at the
4 beginning of the hearing today, the primary customer for this
5 drug were the state Medicare agencies.

6 They were the ones who had to approve the
7 reimbursement, and the primary -- many of the people with AIDS
8 and HIV, as the Court so accurately pointed out, were the most
9 vulnerable people in our health care system; people that had
10 HIV and AIDS; people that didn't have the means to have their
11 own health insurance; and people that were really at the mercy
12 of our health care system. And they got their drugs primarily
13 through the Medicaid systems, through the state that were
14 partially funded by the federal government.

15 And, by the way, the state Medicaid agencies for
16 the record are federal health care programs as defined in 18
17 USC section 24.

18 So these state Medicaid agencies had to approve the
19 drug. The drug, as we mentioned and the Court mentioned, is a
20 very expensive drug, \$21,000 for a 12-week course of treatment.

21 The company aggressively marketed and lobbied the
22 state Medicaid agencies, not just on putting the drug on the
23 formulary, but providing for them the criteria for
24 reimbursement; creating treatment guidelines; using experts
25 that were friends of the company, so to speak, to come

1 together, thought leaders, people respected in their field, to
2 develop guidelines for them to then take to state Medicaid
3 agencies so that the state Medicaid agencies would use as a
4 criteria for reimbursement the BIA test.

5 And they were very successful at doing this; and
6 they were very successful, in particular, in doing it in the
7 top two states that had the highest number of AIDS patients in
8 the country and paid the most for the drug, and that was both
9 California and Florida.

10 So they went to the state Medicaid agencies. We've
11 spoken to the witnesses at the state Medicaid agencies to
12 determine, you know, how those BIA tests were used, and how the
13 criteria was changed to accommodate this BCM wasting.

14 One of the -- and I know we've talked about this,
15 but one of the -- a couple of the tools that the company used
16 to determine or to tell their sales force to talk to people
17 about was -- and, particularly, referring back to your comments
18 a moment ago that you couldn't tell somebody was wasting was a
19 difference -- looking at a muffin, you can't tell the
20 difference between a low fat and a fat-free muffin, but there's
21 a difference in the body composition of that muffin.

22 THE COURT: May I interrupt you just a minute?
23 Because I think -- I don't want to have you tell the whole
24 story and not get to the other part of the case. I'm not sure
25 you haven't covered the area of the conspiracy and the fact

1 that you have an adulterated medical device by saying none of
2 these use the --

3 MS. CARMODY: Were approved by the FDA.

4 THE COURT: -- were approved. I've read the
5 details. I'm not sure you need to add all the details you're
6 about to add.

7 If you think so, you can, but I'm not sure I
8 haven't heard at least the elements I need to determine;
9 namely, the conspiracy and the adulterated device. So I'm
10 suggesting you might want to go on to the second count. Maybe
11 you've already covered the second count.

12 MS. CARMODY: I've covered it to a small point,
13 your Honor, and I will just refer, if there's anything that the
14 Court needs further, to the PSR and the sentencing memorandum
15 with respect to count one.

16 With respect to count two, I'll state it briefly.
17 In early 1999, sales were down with the company. They needed
18 to kick start sales for a number of reasons, including the fact
19 that high-level officials in the company were coming from
20 Switzerland to the United States for a major meeting. There
21 was an international conference on nutrition and HIV infection
22 that was held in Cannes, France on a semi-annual basis. This
23 was the third conference. It was to be held in April of 1999.

24 And in March -- March 1 of 1999, at the Boston
25 Harbor Hotel here in Boston, an emergency meeting was held.

1 Regional directors were coming for another purpose, but they
2 were also asked to come to an emergency meeting that was held
3 by the top management of the unit of Serono Labs that
4 specifically was responsible for the Serostim sales -- and
5 that's the metabolic and immune therapy unit at the time, often
6 called M&IT -- and the top management, which included the vice
7 president of sales, who was Mary Stewart, and the vice
8 president of marketing, who was John Bruens, both of them are
9 individuals who have been indicted in a related case on this
10 specific conspiracy.

11 Serono Labs knew that the offering and inducement
12 to a physician to get them to refer a patient or write
13 prescriptions for Serostim so they would then take it to a
14 pharmacy and had it filled, including at a Medicaid agency,
15 they knew that was wrong. They had had training on kickbacks,
16 so they knew that.

17 But at the end of February of 1999, they were only
18 meeting 80 percent of their sales goal. They needed to kick
19 start sales. So on March 1st, they had a meeting. The vice
20 president of marketing, the vice president of sales, and other
21 top management called together the regional directors. The
22 country at that time for its sales purposes were divided into
23 six regions, each led by a regional director.

24 So they pulled in those regional directors, one of
25 whom was Adam Stupak, who has pled guilty in a related case and

1 is awaiting sentencing; one of whom is a relator in a civil
2 case; and spoke to the regional directors about kick starting
3 sales, and, in particular, targeting high prescribers to go to
4 the conference in Cannes in return for writing -- at that time
5 the plan was writing 30 scripts for the trip.

6 The regional directors then, taking their orders
7 from top management, went out and some of the regional
8 directors did exactly what their top management told them to
9 do. And, in particular, Adam Stupak would testify that he went
10 out and offered -- made the offer to three doctors in New York
11 and the doctors not just in New York but in other areas of the
12 country, some of them accepted it, some of them rejected it,
13 and some of them, you know, simply walked away from it.

14 Some of them accepted it and went, some of them
15 didn't accept it at first and went. But the bottom line was
16 that two -- at least two of the doctors told their sales
17 representatives that this was not an appropriate offer and that
18 it was -- calling it -- so much as calling it a bribe.

19 And that information even went back to top
20 management through the regional directors and still they
21 continued on with the program.

22 Approximately 20 doctors were offered the trip, 13
23 accepted the trip.

24 I think that should be sufficient on count two,
25 your Honor.

1 THE COURT: Well, let me ask you. I have a
2 question about count two, and the question is: Who are the
3 conspirators?

4 MS. CARMODY: The conspirators were the executive
5 vice president who led the marketing -- the Serostim business
6 unit, but in particular, the conspirators were Mary Stewart,
7 who was the vice president of sales; John Bruens, the vice
8 president of marketing; the regional directors; in particular
9 Adam Stupak; and the regional directors that are charged in a
10 related indictment, Marc Sirockman and Kimberly -- Melissa
11 Vaughn, excuse me.

12 THE COURT: Help me understand. These people all
13 work for the corporation.

14 MS. CARMODY: Yes, your Honor.

15 THE COURT: So they are agents of the corporation.

16 MS. CARMODY: Yes, your Honor.

17 THE COURT: The corporation acting only through its
18 agents.

19 The corporation is a co-conspirator -- is a
20 conspirator. Are you saying that the individual people who
21 acted for the corporation are also the conspirators? You
22 follow me?

23 MS. CARMODY: I can tell you how the corporation
24 acted to -- your Honor, I think what you're asking me is are
25 they acting ultra vires?

1 THE COURT: No, that's not what I'm asking.

2 I'm asking -- the defendant before me is the
3 corporation.

4 MS. CARMODY: Right.

5 THE COURT: And my question is, the defendant is
6 charged with conspiracy, there have to be two people, two
7 conspirators. The corporation is a conspirator, and I'm asking
8 you who is the other conspirator or the other conspirators?
9 And your answer initially were these people who work for the
10 corporation; and as to that I'm just asking you if those people
11 can be conspirators, since they were, in fact, acting for the
12 corporation?

13 MS. CARMODY: Yes, they can, I think, your Honor.

14 THE COURT: Well, you think -- I mean, I don't --
15 is that right? Can they be conspirators? Maybe they can, I
16 guess I don't -- I guess I'm not saying they can't, I just need
17 to know that.

18 Mr. Depippo, you represent the corporation. I just
19 need to understand this legal question. I'm asking a legal
20 question. I'm asking to both of you a legal question.

21 MR. DEPIPPPO: Judge, I always understood the
22 conspiracy to involve the corporation and certain physicians.
23 There are a number of people outside of the corporation --

24 THE COURT: Perhaps they are. The physicians, I
25 assume, were the offerees. The conspiracy is charged as a

1 conspiracy to offer. So the question, even with respect -- I
2 thought about your position. The question I have is whether a
3 physician -- perhaps you're right, perhaps a person who is the
4 offeree can be a co-conspirator, but only -- I assume only can
5 be the person who accepts the offer.

6 MR. DEPIPPO: Right. And I think they've
7 articulated, at least the way I've always read count two, is
8 that certain physicians did accept the offer.

9 THE COURT: I understand. But you understand the
10 conspiracy crime is complete when -- at the conspiracy level,
11 not when the crime is carried out.

12 MR. DEPIPPO: When the agreement is made.

13 THE COURT: The agreement. And the agreement is to
14 do an illegal act. The illegal act charged is offering to pay
15 illegal remuneration. As a kind of intellectual matter, I'm
16 having trouble understanding the offeree conspiring to offer.

17 MS. CARMODY: I think I can help.

18 THE COURT: Okay.

19 MS. CARMODY: Corporate policy, the top management,
20 the vice president of sales and marketing held a meeting in
21 Boston where they told regional directors to go and make this
22 offer.

23 THE COURT: Yes.

24 MS. CARMODY: Now, they were employees of the
25 corporation, but they're also individuals. They could choose,

1 that was their choice, the individual regional directors, to
2 participate in this conspiracy or not. And, in fact, that was
3 the case. Some regional directors went out and joined the
4 conspiracy, joined the agreement and went out and made the
5 offers to doctors and made the payments. Not every regional
6 director has been charged in this case nor is it alleged that
7 every regional director participated.

8 THE COURT: I see.

9 MS. CARMODY: There were others that recognized the
10 wrongness of this corporate policy and decided and determined
11 not to participate in it.

12 THE COURT: Okay. Let me understand now. So the
13 corporation, acting through its executives, the people you
14 identified, the exec --

15 MS. CARMODY: John Bruens and Mary Stewart, among
16 others.

17 THE COURT: Who are they?

18 MS. CARMODY: They were the vice president of sales
19 and the vice president of marketing.

20 THE COURT: So they act for the corporation.

21 MS. CARMODY: Yes.

22 THE COURT: They go to employees and they say go
23 out and make these offers.

24 The people whom they direct, understanding,
25 presumably, this is illegal to do this, agree with the

1 corporation through its executives to go out and make these
2 offers.

3 MS. CARMODY: That's correct.

4 THE COURT: Okay. And so you say that when they
5 agree, they're acting as individuals, not as agents of the
6 corporation.

7 MS. CARMODY: Because they're not corporate
8 officers; they're employees.

9 THE COURT: Okay. All right.

10 MS. CARMODY: Okay.

11 THE COURT: All right.

12 MS. CARMODY: Does the Court have any other
13 question on count two?

14 THE COURT: I don't think so.

15 MS. CARMODY: Okay. So I'll refer any other facts
16 that I have not stated in open court to the sentencing
17 memorandum incorporate that, and that would be our evidence on
18 count one and count two, your Honor.

19 THE COURT: Mr. Depippo, do you have anything you
20 want to add? This is the government's presentation.

21 You're satisfied with the explanation given to me
22 by Ms. Carmody that the conspiracy was the corporation
23 conspiring with certain of its employees to violate this
24 statute?

25 MR. DEPIPPPO: Judge, I would also -- and again, the

1 way I always read that was that would include --

2 THE COURT: Doctors.

3 MR. DEPIPPO: Would include doctors.

4 THE COURT: Well, I'll include them for this
5 purpose, because I am persuaded by the employees. The doctors
6 I have a less comfort with, because, as I say, the doctors --
7 the charge is conspiring to offer. This is not conspiring
8 to -- it's not a bribery conspiracy in the sense that -- maybe
9 it is, but I'm just looking at the language, the conspiracy to
10 offer. Maybe the offeree can be a conspirator.

11 MR. DEPIPPO: I was going to say I just read it
12 broadly, it's a conspiracy to violate the anti-kickback
13 statute, which certainly can be violated by a physician who
14 agrees to accept the payment.

15 THE COURT: All right. Fair enough. It's just the
16 language of the information was a little -- I had a little
17 concern with the use of conspiracy, language of the
18 information.

19 Let me ask you, Mr. Gunning -- please, if you'll
20 stand again -- did you hear all the things that Ms. Carmody
21 said?

22 MR. GUNNING: I did.

23 THE COURT: Do you have any questions about
24 anything she said?

25 MR. GUNNING: I don't.

1 THE COURT: Do you agree; that is to say, do you
2 disagree with anything she said?

3 MR. GUNNING: Yes. We don't agree with all of the
4 facts in the information or the sentencing memo, but I did
5 understand your explanation of the material elements of the
6 crimes, and we agree to the facts that would support those
7 elements.

8 THE COURT: You have the government's sentencing
9 memorandum?

10 MR. GUNNING: As of yesterday afternoon, yes.

11 THE COURT: And you read it?

12 MR. GUNNING: Yes.

13 THE COURT: What facts do you disagree with as
14 recited by Ms. Carmody and in the memorandum?

15 MR. GUNNING: I can try to give some examples, but
16 I can't give you a laundry list --

17 THE COURT: Well, I ask this question, because,
18 depending on what facts you disagree with, you may be
19 disagreeing with the crime that was committed. It may be that
20 you're talking details, maybe this sale wasn't made, that sale
21 wasn't made, but some sales were made. Maybe there were three
22 software packages, not four, details of that kind. If that's
23 the thing you're talking about, okay -- I just need to know,
24 because I need to know whether you are actually admitting to
25 these crimes.

1 MR. GUNNING: I think it's detail, I think if we go
2 on to some of the things we agree with --

3 THE COURT: Maybe that would be helpful. Yes, that
4 would be helpful.

5 MR. GUNNING: I guess in the late 1990s we agree
6 that Serono Labs with RJL introduced the BIA machines that
7 contain software that was not approved by the FDA.

8 THE COURT: Okay. All right. And how about with
9 respect to count two?

10 MR. GUNNING: I guess as to count two, Serono
11 Laboratories also agreed to make payments to certain physicians
12 in the form of a trip to Cannes, France to attend a medical
13 conference.

14 THE COURT: And this agreement was with the
15 employees, the regional directors --

16 MR. GUNNING: The payments were made to physicians.

17 THE COURT: The payments were made, but who is it
18 that you agreed with the regional directors that they should go
19 out and make these offers?

20 MR. GUNNING: I guess on this point, at least as I
21 understand the information, it's a conspiracy to offer and pay
22 remuneration to physicians.

23 THE COURT: All right. Then let me ask you it this
24 way: Ms. Carmody explained what happened. There was a
25 meeting, two executives from the company came, and they

1 instructed regional directors to go out to get employees to
2 make these offers. Have I summarized what you said?

3 MS. CARMODY: Yes, your Honor.

4 THE COURT: Do you agree with that much?

5 MR. GUNNING: Can I consult just for a minute?

6 THE COURT: You certainly may.

7 (Discussion off the record.)

8 MR. GUNNING: I guess we acknowledge that Adam
9 Stupak, one of our former employees, has pled guilty. We also
10 acknowledge -- understand that the other individuals that have
11 been charged are contesting their guilt.

12 THE COURT: Well, that's not the same thing as
13 agreeing that the corporation -- Ms. Carmody said that the two
14 executives of the corporation had a meeting at the Boston
15 Harbor Hotel and instructed or directed regional directors to
16 go out or have people working for the regional directors to go
17 out and make offers to physicians that if they were to
18 prescribe the drug -- Ms. Carmody?

19 MS. CARMODY: Yes, your Honor.

20 THE COURT: -- to prescribe the drug in sufficient
21 numbers, 30, I think, they would get this trip to this
22 conference in France; and that 20 of such offers were made
23 pursuant to this direction, and 13 people went to that
24 conference. I think that's what you said.

25 MS. CARMODY: Yes, your Honor.

1 THE COURT: All right. Does the company agree --
2 does the company admit that that happened?

3 (Mr. Gunning conferred with counsel.)

4 MR. GUNNING: The numbers and the details are -- I
5 have a hard time confirming those facts. We do know that some
6 offers were made and some payments were made to physicians in
7 order to attend a conference in Cannes, France.

8 THE COURT: Work with me, Mr. Gunning. If the
9 company doesn't want to acknowledge a central fact, that's not
10 a problem for me. Here's what I'm asking: The government's
11 position is that the corporation conspired to make offers to
12 doctors. And so the question I ask you, does the company admit
13 the facts as recited by Ms. Carmody relative to the conspiracy
14 to make this offer to physicians? And the facts that she
15 recited are the ones I just mentioned, that this meeting was
16 held at the Boston Harbor Hotel. That's part of what she
17 said. A meeting -- sales were not going well, the meeting was
18 held at the Boston Harbor Hotel, regional directors were
19 invited, six regional directors -- I'll let you consult with
20 your lawyer if you want to, then I'll tell you what I want you
21 to hear from me.

22 MR. GUNNING: I'm sorry, I'm being distracted.

23 THE COURT: You consult and tell me when you're
24 ready.

25 (Mr. Gunning conferred with counsel.)

1 THE COURT: Okay, sir.

2 MR. GUNNING: So let me give this a try.

3 Serono Laboratories also agrees that it and at
4 least one company employee conspired to make payments in the
5 form of a free trip to Cannes, France for physicians.

6 THE COURT: Okay. Thank you, sir.

7 MR. GUNNING: Thank you.

8 Ms. Carmody, do you see any reason why I should not
9 take the plea of the corporation?

10 MS. CARMODY: No, I do not.

11 THE COURT: Mr. Depippo, do you see any reason why
12 I should not take the plea of the corporation?

13 MR. DEPIPPPO: No, your Honor.

14 THE COURT: To these two counts?

15 MR. DEPIPPPO: No, your Honor.

16 THE COURT: All right. Mr. Gunning, please stand.

17 THE CLERK: Mr. Gunning, Serono Laboratories has
18 been named in two counts in an information charging in count
19 one conspiracy to introduce into interstate commerce, with
20 intent to defraud and mislead, adulterated medical devices in
21 violation of Title 18 United States Code 371; and in count two
22 with conspiracy to offer to pay illegal remuneration to health
23 care providers in violation of Title 18 United States Code
24 section 371.

25 How do you plead to counts one and two of the

1 information, guilty or not guilty?

2 MR. GUNNING: Guilty.

3 THE COURT: It is the finding of the Court that
4 Mr. Tom Gunning is an officer of the defendant corporation
5 Serono Laboratories, Incorporated and that the board of
6 directors of that corporation empowered him to waive indictment
7 of the corporation of the two charges set forth in the
8 information; that Mr. Gunning is -- was likewise authorized by
9 the directors of the corporation to enter a plea of guilty to
10 the two counts of the information; and that the corporation is
11 financially able to pay the fine set forth in the plea
12 agreement between the United States and the corporation; that
13 the corporation is aware of the nature of the charges in the
14 information and the consequences of pleading guilty to those
15 charges; and, finally, that the plea of guilty that Mr. Gunning
16 has entered on behalf of the corporation is a knowing and
17 voluntary plea supported by an independent basis in fact
18 containing each of the essential elements of each of the
19 offenses charged in the information.

20 I will determine that the corporation may be found
21 guilty of these two offenses. Acceptance of this plea,
22 however, I will await information that I receive in the
23 specific sentencing phase.

24 So let's proceed to the sentencing phase.

25 I normally ask, but I don't think it's really

1 necessary in this case, whether you, Ms. Carmody, have seen the
2 presentence report.

3 MS. CARMODY: I have, your Honor.

4 THE COURT: Mr. Depippo, have you seen it?

5 MR. DEPIPPPO: Yes, your Honor.

6 THE COURT: And have you discussed it with the
7 corporation?

8 MR. DEPIPPPO: I have, your Honor.

9 THE COURT: And specifically with Mr. Gunning?

10 MR. DEPIPPPO: I have, your Honor.

11 THE COURT: Let me take a moment, first, to thank
12 our splendid probation office generally and particularly
13 Ms. Sinclair, who has worked on this presentence report.

14 This was not an easy report to do. I see lots of
15 presentence reports. Ms. Sinclair has worked with me in lots
16 of criminal cases and has prepared many, many splendid
17 presentence reports; but the work involved in this one was
18 enormous, and so I want to take a moment to thank her
19 particularly and the probation office for the fine work that
20 has gone into preparing this presentence report.

21 I want to thank Ms. Sinclair in particular for the
22 help she's giving me in understanding the presentence report,
23 to the extent I have any understanding of it -- let me say I
24 have some understanding of it. As you know, I started off
25 getting the numbers wrong. But after so many numerals, I'm

1 lost. Math was not my best subject; arithmetic was not my best
2 subject, so whatever fault there is in my getting these numbers
3 mixed up in the beginning of this proceeding is my fault. But
4 I want everybody to know that our probation office has done a
5 magnificent job here. Ms. Sinclair has done a wonderful job
6 putting it all together and particularly in explaining to
7 somebody who is as dense as I am about these matters.

8 So I want to say that before we begin.

9 Let me then recite what the guidelines provide in
10 this case, starting with the offense level computation.

11 What page is that?

12 PROBATION OFFICER: 46.

13 THE COURT: The guideline manual applicable to this
14 case is the manual in effect at the time of the commission of
15 the offense; that is to say, the manual of November 1, 2001.
16 The probation department has determined that these guidelines
17 are more beneficial to the corporation with respect to the loss
18 calculation and the number of victims than the guidelines --
19 the current guidelines or the guidelines at the time of
20 sentencing.

21 On the basis of the 2001 guideline manual, the
22 probation officer, using the procedures for determining
23 guidelines organizations, including the culpability score
24 computation, the probation officer has determined that the
25 total culpability score of this corporation in these

1 circumstances is six, taking account the offense level
2 computation of both of the two counts of conviction.

3 The culpability score of six results in a fine
4 multiplier of 1.2 at the minimum level and 2.4 at the maximum
5 level, and a statutory maximum of \$228,224,000.

6 All right. Have I stated that correctly as far as
7 the United States is concerned, Ms. Carmody?

8 MS. CARMODY: Yes, your Honor.

9 THE COURT: Mr. Depippo, have I stated that
10 correctly as far as the corporation is concerned?

11 MR. DEPIPPPO: Yes, your Honor.

12 THE COURT: All right. Now, are there objections
13 to the culpability score at all? I guess I stated it
14 correctly, but I suppose I specifically should ask if there are
15 objections.

16 Does the government have any objection?

17 MS. CARMODY: No, your Honor.

18 MR. DEPIPPPO: Not to this Court.

19 THE COURT: I'm sorry, sir?

20 MR. DEPIPPPO: Not to this Court.

21 THE COURT: You have objection to something?

22 MR. DEPIPPPO: No, your Honor. We have no
23 objections to the presentence report that need to be resolved
24 by the Court.

25 THE COURT: That's fine

1 All right. Then let me proceed to state that the
2 fine range as determined by the parties on this plea is
3 \$136,935. The fine --

4 MR. DEPIPPO: Judge, I'm sorry, it's \$136 million.

5 THE COURT: I told you.

6 Thank you. Don't let me do that again. Somebody
7 stop me.

8 The guideline fine range as determined by the
9 parties in accordance with their agreement is \$136,936,000 to
10 \$2,868,800 is the range. And the parties have agreed that the
11 fine to be paid by the corporation is \$136,936,000.

12 Have I stated that correctly at long last,
13 Ms. Carmody?

14 MS. CARMODY: Yes, you have, your Honor. I just
15 want to make one point. In fact, I think the parties agree on
16 this, that the fine range I think has to be capped with a
17 statutory maximum.

18 THE COURT: Yes. I should have said the range is
19 \$136,936,000 to \$273,868,800. There's a statutory cap of
20 \$228,224,000.

21 MS. CARMODY: That's correct, your Honor.

22 THE COURT: So the range in effect is \$136,936,000
23 to \$228,224,000.

24 MS. CARMODY: That's correct, your Honor.

25 THE COURT: Okay.

1 Correct, Mr. Depippo?

2 MR. DEPIPPPO: Yes, your Honor.

3 THE COURT: Okay. Now, the parties have agreed
4 that the fine should be the low end of the guideline range, and
5 I won't recite the number again because I've said it correctly
6 once and I don't want to mess it up.

7 The special assessment, mandatory special
8 assessment on the two counts of conviction is \$800. There is a
9 guideline range of probation of one to five years, and the
10 parties have agreed that no probation is appropriate.

11 Have I stated that correctly, counsel?

12 MS. CARMODY: Yes, your Honor. And just to explain
13 to the Court the reason, the company has agreed as part of the
14 global resolution to enter into and has entered into a
15 corporate integrity agreement with the Office of Inspector
16 General for the Department of Health and Human Services; and
17 that term is at least five years. And that oversight would be
18 essentially more, actually, than I think a probation officer
19 could do, and is more appropriate in these circumstances.

20 THE COURT: I think that's right.

21 We come now to the question on whether I can accept
22 this plea on the basis of this agreement, and I have the
23 question that I raised earlier in the proceeding having to do
24 with the failure of the parties' agreement to take -- well,
25 that's not an accurate statement. I'm sorry, Ms. Carmody and

1 Mr. Depippo. I was going to say the failure to take into
2 account the individuals, and I appreciate that you took them
3 into account. That would be an inaccurate statement.

4 I understand that the position of the parties to be
5 that the complications of a restitution program for the
6 individuals outweigh -- or the value of the global arrangement
7 that the parties have entered into substantially outweighs the
8 omission, any consequence of omitting any provision for the
9 individual victims. Have I stated at that correctly?

10 MS. CARMODY: That's correct, your Honor. That's
11 our position.

12 THE COURT: Okay. Mr. Depippo, can you speak to
13 this question? Because it's -- if I am correct that some 9,000
14 individuals -- and I'm primarily concerned with the individuals
15 as opposed to the private corporate victims -- if there are
16 9,000 individuals who may have been injured, isn't there
17 something that might be done for those 9,000 that does not
18 unreasonably burden the parties in administering the program?

19 MR. DEPIPPPO: Judge, a couple of things.

20 I mean, first, you know, there's a substantial
21 portion of the restitution award in this case that relates to
22 civil theories that are outside of counts one and count two.

23 THE COURT: I understand that.

24 MR. DEPIPPPO: And as part of that global civil
25 settlement, with respect to those theories, the company has not

1 admitted to any liability. And so -- I mean, as an initial
2 matter, there certainly will be, you know, a question as to
3 whether those people have suffered any harm or any loss at
4 all. And I think that there -- secondly, there would be a
5 mechanism whereby -- and, in fact, is a mechanism whereby any
6 harm would be redressed; and that is to say -- I'm not handling
7 it, I'm not fully up to speed, but I'm well aware there is a
8 civil suit that has been filed that purports to be a class
9 action suit at least -- and as I understand it, it is filed on
10 behalf of those that are the non-Medicaid payees of this drug.
11 And so it seems to me that not only are there all of the
12 complications, but there is also an alternative forum under
13 which anyone who has been harmed can seek compensation.

14 THE COURT: I'm surprised I didn't think about the
15 class action mechanism.

16 All right. I think you have addressed my problem,
17 because, as I say, I am satisfied that the private insurers can
18 take care of themselves; and oddly enough, Mr. Depippo -- not
19 oddly enough for him, oddly enough for me, I didn't think of
20 it, that there is a forum and the mechanism for the
21 individuals, and that is a class action. Class action isn't
22 easy, but it may be the best mechanism for any person who
23 thinks of himself or herself injured by the company as a result
24 of this scheme, because there will be a judicial, as
25 distinguished from an administrative or alternative dispute

1 resolution, mechanism available to such person.

2 There is one thing, however, that it seems to me
3 that should be -- and I just want to put this on the table, and
4 maybe I don't have to do this, because maybe the fact of this
5 plea and the fact of this global settlement will become public
6 knowledge; just because of the size and of the nature of it, it
7 will become public knowledge, but my thought had been that
8 there might some means by which the company could communicate
9 directly with people who may have been injured by providing
10 information for physicians who prescribed the drug pursuant to
11 this -- during the time of this conspiracy, a notice in the
12 doctor's office, for example, so that people know that if they
13 have claims, that they can make those claims before any statute
14 of limitation runs.

15 What about that?

16 MR. DEIPPPO: Judge, as I understand it, when the
17 plea agreement was announced in October, it was done at the
18 highest levels, including the Attorney General of the United
19 States. It received much fanfare in the media, and there has
20 been, if you will, a public dissemination of these proceedings.

21 THE COURT: What does the United States think about
22 that, Ms. Carmody?

23 MS. CARMODY: Well, your Honor, on October 17th,
24 Attorney General Gonzales did make the announcement of the
25 global resolution, including the government's agreement to

1 plead guilty in this case.

2 It did receive a lot of newspaper coverage, so that
3 individuals, particularly physicians who may have been
4 prescribing the drug, would have received or been able to
5 access the information with respect to this.

6 THE COURT: If they happened not to be watching TV
7 that day or didn't read the newspaper, they don't know.

8 I guess I need to ask you, Ms. Carmody, as a
9 representative of the United States whether what I've just
10 suggested is so fractious to this understanding that I
11 shouldn't think about it any further?

12 MS. CARMODY: I'm not sure that it fractures the
13 understanding, your Honor; but I think it's certainly
14 something -- I know that we have considered in the context of
15 our obligations with respect to the victims of the offense.

16 I think that certainly all the Medicaid agencies
17 are aware of it, all the insurers are aware of it. With
18 respect to physicians, physicians are aware of this case.

19 THE COURT: Well, you mean they're aware of it
20 because there's been a newspaper -- other publicity about it.

21 MS. CARMODY: I think it's more than that, your
22 Honor. In my experience in the investigation the number of
23 physicians who are physicians who would prescribe this drug are
24 not a lot in terms of all of the physicians in the United
25 States. They're usually infectious disease doctors or doctors

1 who specialize in treating AIDS patients. That is a very small
2 medical community in the context of the whole medical community
3 of the United States. So that those doctors are very well
4 connected with respect to issues such as this.

5 There are a lot of AIDS activists and AIDS -- there
6 are several and very vocal groups of advocates for patients
7 with AIDS and HIV who have been -- in fact, one was a relator
8 in one of the civil actions in California, so that those AIDS
9 activist groups are very well aware of that settlement and take
10 on the role of advising patients who may be out there.

11 THE COURT: Is there some nationally recognized
12 single or two or three --

13 MS. CARMODY: Advocacy groups.

14 THE COURT: Advocacy groups, I'm thinking about
15 something like the Muscular Dystrophy Association -- I don't
16 mean -- a group like that for people who are HIV and AIDS
17 infected. Is there a group like that? There must be.

18 MS. CARMODY: There are regional groups, your
19 Honor, for sure. And they're very activist groups,
20 particularly, for example, in California, New York, Florida,
21 some of the major payers for this drug.

22 I don't know of any one national agency, there must
23 be, and we can certainly -- I mean, even with respect to the
24 government's obligation, we could notify that -- whatever
25 groups, major groups that we could identify. That would be not

1 be a burdensome task I would think.

2 THE COURT: I think that as part of this
3 arrangement, and before I can accept the arrangement, and I
4 want to add a provision, which I should tell you, Mr. Gunning,
5 when I add it you will have the opportunity to withdraw this
6 plea, but I want to add a provision that requires the
7 cooperation with the United States and particularly with the
8 United States attorney's office in this district in
9 disseminating information -- I think if you tell me this will
10 be sufficient -- to appropriate advocacy organizations
11 throughout the United States about the proceedings here, that
12 there has been a plea of guilty to these counts, there is a
13 global settlement. That's all you need to say. Explain what
14 the plea is, what the global settlement seeks to accomplish in
15 some manner. I think if the parties will agree to this, I can
16 agree to this plea, but I do think that I want -- ideally I'd
17 like it to go to all of these 9,000 people, but since there's
18 some difficulty in deciding who those 9,000 are -- isn't that
19 the problem? You don't know who the 9,000 are?

20 MS. CARMODY: We have not -- I don't know that we
21 can identify them specifically. We have tried. I've actually
22 had agents try to make some kind of a list to notify, that's
23 how we came up with the numbers that we do, but we know that
24 our list is woefully inadequate, your Honor; and I wouldn't
25 pretend to represent to the Court that I have an absolute list

1 of patients.

2 We have numbers from company documents. Part of
3 the issue with AIDS patients is there's an awful lot of privacy
4 concerns.

5 THE COURT: Of course.

6 MS. CARMODY: So that we may not have names of
7 patients; and, in fact, in many instances, even when we got
8 patient records to review, names were not identified.

9 I think that we can manage -- and I haven't had a
10 chance to talk to Mr. Depippo and Mr. Gunning yet, but with
11 respect to -- I know our obligations under the victim/witness
12 statute we have ways to do a dissemination of information. So
13 if we need to identify -- what I'm concerned about is what the
14 Court considers appropriate or sufficient.

15 THE COURT: Well, you're right. I haven't been
16 very specific, because I don't know how to be specific about
17 this.

18 You told me a minute ago that the medical community
19 regularly treating AIDS patients is relatively small.

20 MS. CARMODY: When I say relatively small, I think
21 it's about --

22 (Discussion off the record.)

23 MS. CARMODY: -- 50,000.

24 MR. DEPIPPPO: It's a close-knit group, and they
25 stay aware of developments.

1 As you know with AIDS, there's a new development
2 you know every other day. It's not like some of these other
3 diseases. And so they are -- I think that they're fairly
4 characterized as a group of physicians that stay on top of
5 things.

6 THE COURT: Well, one group of physicians I wonder
7 can be those physicians who -- do we know who those physicians
8 are who --

9 MS. CARMODY: The company has lists of physicians
10 that prescribe this drug. There's absolutely no question about
11 that, your Honor.

12 THE COURT: For purposes for which the government
13 claims were unlawful.

14 MS. CARMODY: Yes.

15 THE COURT: Why don't we use that list and send
16 this information to those physicians?

17 MS. CARMODY: To those physicians?

18 THE COURT: To those physicians.

19 MS. CARMODY: Rather than advocacy groups?

20 THE COURT: And advocacy groups.

21 MR. GUNNING: Your Honor, I feel that my authority
22 is limited by what the board of directors has considered.

23 THE COURT: I certainly understand that.

24 MR. GUNNING: So I don't feel that I could make
25 that kind of commitment on behalf of the company.

1 I do -- we would not have an objection if the
2 government went with its press releases to the advocacy groups.

3 THE COURT: Here's what I would like to do,
4 Mr. Gunning. I understand your position. Why don't I take a
5 recess until sometime next week, and you can consult, see if
6 you can get that authority. Because I want that done.

7 I will accept this plea if I can get that done. If
8 I can get the communication to the advocacy groups of the
9 doctors that the company has pleaded guilty and there has been
10 this global settlement -- and you show me what it is you're
11 going to tell me, and then I can be satisfied that the people I
12 think who have been -- who individually have been harmed know
13 about it, and they can take whatever action they want to take.

14 MS. CARMODY: Your Honor, may I have a moment to
15 consult? But I think we can do that in the U.S. Attorney's
16 Office.

17 THE COURT: The government will undertake this?

18 MS. CARMODY: I'd like to confirm that, but I think
19 we might be able to.

20 If I may just have a moment to confer.

21 THE COURT: I'll take five minutes, a recess, and
22 you confer.

23 MS. CARMODY: Thank you.

24 THE COURT: And if the government will undertake
25 that responsibility -- understand I don't know who the advocacy

1 groups are, but you can find out; and I want the information
2 from the company to you as to whom the doctors were.

3 I'll take five minutes and you can tell me whether
4 you can do it. We can wrap this up today.

5 MS. CARMODY: Thank you, your Honor.

6 THE COURT: Thank you.

7 (Recess taken.)

8 THE COURT: Ms. Carmody, what can you --

9 MR. DEPIPPPO: Your Honor, may I address the Court?

10 THE COURT: Yes.

11 MR. DEPIPPPO: Judge, I want to put on the record
12 what I think should satisfy the Court to conclude these
13 proceedings today, and I've had discussions with the
14 government; and that is, that the government and the company
15 will work together to identify and agree on the prescribing
16 physicians and appropriate AIDS advocacy groups to whom the
17 company will send a notice of the global settlement and this
18 plea.

19 THE COURT: Okay. That satisfies me.

20 I need to know how I implement this in terms of the
21 sentencing. There's no term of probation, and so I -- maybe
22 it's enough that I have this representation on the record, and
23 that will be sufficient --

24 MR. DEPIPPPO: Judge, it's our view that is
25 sufficient as long as the government concurs on the record.

1 THE COURT: Let me ask my expert here to my left.

2 PROBATION OFFICER: It seems to me that it could be
3 sufficient, your Honor, because since it could have otherwise
4 been incorporated in the plea agreement as part of their other
5 agreements. But I'm not certain.

6 MS. CARMODY: Your Honor, we do could it by way of
7 an addendum to the plea agreement.

8 THE COURT: That would be sufficient. All right.
9 And since I am agreeing to accept this plea on the conditions
10 set forth in the plea agreement, if that is added to the plea
11 agreement, that will be a way to implement this added
12 provision.

13 Mr. Gunning, if you'll stand, please. And thank
14 you and Mr. Depippo and Ms. Carmody for taking the few minutes
15 it took to satisfy me by adding that provision.

16 MR. GUNNING: No problem.

17 THE COURT: Now that you have added the provision,
18 I should formally ask whether with the condition that I've
19 added to -- that I insist be added to the plea agreement, does
20 the company wish to withdraw its plea?

21 MR. GUNNING: No.

22 THE COURT: All right.

23 Then, Ms. Carmody, do you see any reason why I
24 should not impose sentence?

25 MS. CARMODY: No, your Honor.

1 THE COURT: Mr. Depippo.

2 MR. DEPIPPPO: No, your Honor.

3 THE COURT: Pursuant to the Sentencing Reform Act,
4 Mr. Gunning, and having considered the sentencing factors
5 enumerated at Title 18 United States Code section 3553(a) and
6 the plea agreement of the parties, as modified in the way we
7 have just discussed on the record, it is the judgment of the
8 Court that the corporation, Serono Laboratories, Inc., shall
9 pay to the United States a fine of \$136,936,000. That fine
10 shall be paid within seven days of the imposition of this
11 sentence.

12 The fine is to be continued to be paid until the
13 full amount, including interest, has been paid. And by that I
14 mean, if it's not paid within that seven days, those interest
15 penalties will continue to accrue.

16 It's further ordered that Serono Corporation shall
17 comply with the terms of the Rule 11(c)(1)(e) plea agreement as
18 modified --

19 MR. DEPIPPPO: Just for the record, that's Serono
20 Laboratories, Inc.

21 THE COURT: What did I say?

22 MR. DEPIPPPO: You said Serono Corporation.

23 THE COURT: Thank you.

24 It's further ordered that the defendant, Serono
25 Laboratories, Inc., shall comply with the terms of the

1 Rule 11(c)(1)(e) plea agreement as modified today and the
2 settlement agreement entered into by the parties, including,
3 but not limited to, the payment to the United States and
4 participating -- Medicaid participating states collectively the
5 sum of \$567,065,000 together with interest as set forth in
6 paragraph one of the settlement agreement.

7 It is further ordered that the defendant, Serono
8 Laboratories, Inc., shall pay the United States a required
9 special assessment of \$800, which shall be due and payable
10 immediately.

11 Are there any questions of anyone? Of me from
12 anyone?

13 MR. GUNNING: No.

14 MS. CARMODY: No, your Honor.

15 THE COURT: Let me advise -- no question.

16 Let me advise the corporation through you,
17 Mr. Gunning, that the corporation has the right to appeal this
18 conviction if the corporation finds there's some fundamental
19 defect in these proceedings not waived by the corporation's
20 guilty plea.

21 The corporation also has a right to appeal the
22 sentence to the extent that right has not been modified or
23 waived by the corporation in the plea agreement.

24 Any appeal that the corporation wishes to file must
25 be filed within ten days of judgment being entered in this

1 case.

2 Is there anything further, counsel, and
3 Mr. Gunning?

4 MR. GUNNING: No.

5 THE COURT: If there's nothing further, then thank
6 you very much for your cooperation for getting this matter
7 settled.

8 We are adjourned.

9 (Court adjourned at 1:15 p.m.)

10 i i i i i i i

11 CERTIFICATION

12 I certify that the foregoing is a correct
13 transcript of the record of proceedings in the above;entitled
14 matter to the best of my skill and ability.

15
16
17
18 _____
19 Debra M. Joyce

Date

20 Official Court Reporter
21
22
23
24
25